

We claim:

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1 A method for preparing microcrystalline cellulose granules comprising the following steps:

5 (a) granulating microcrystalline cellulose with a granulating fluid comprising water and a water-miscible, volatile, polar organic solvent to provide a granulated microcrystalline cellulose;

(b) drying the granulated microcrystalline cellulose at a controlled rate for a time sufficient to remove at least substantially all of the polar organic solvent from the granulated microcrystalline cellulose and without extruding or spheronizing the granulated microcrystalline cellulose from granulation step (a); and

10 (c) removing at least a substantial portion of the water from the granulated microcrystalline cellulose.

2. The method of claim 1 wherein said polar organic solvent is selected from the group consisting of methanol, ethanol, propanol, isopropanol, t-butyl alcohol and acetone.

3. The method of claim 2 wherein said polar organic solvent is isopropanol.

4. The method of claim 1 wherein the volume ratio of water to said polar organic solvent in said granulating fluid is from 85:15 to 15:85.

5. The method of claim 1 wherein the ratio of said granulating fluid to said microcrystalline cellulose in the granulating step is from 1:2 to 2:1.

6. The method of claim 1 wherein said granulated microcrystalline cellulose is initially dried at controlled temperature and pressure and once substantially all of the polar organic solvent is removed, further drying is carried out at one or more of an elevated temperature, reduced pressure or both.

7. The method of claim 1 further comprising the step of adding to the granulated microcrystalline cellulose about 1% to about 30% by weight of a hydrocolloid, based on the weight of the granulated microcrystalline cellulose.

8. The method of claim 7 wherein the hydrocolloid is added to the granulated microcrystalline cellulose prior to the drying step which removes substantially all of the polar organic solvent component from the granulated microcrystalline cellulose.

9. The method of claim 7 wherein the hydrocolloid is added to the microcrystalline cellulose granules after substantially all of the polar organic solvent has been removed from the granulated microcrystalline cellulose.

10. The method of claim 7 wherein in the adding step the hydrocolloid is coated onto the surface of the microcrystalline cellulose granules.

11. The method of claim 7 wherein the hydrocolloid comprises one or more hydrocolloids selected from the group consisting of: methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, hydroxypropyl methylcellulose, gelatin, water soluble cellulose acetate, polyvinyl pyrrolidone, starches, alginates, alginic acid, locust bean seed extract, guar seed extract, carrageenan, gum tragacanth, gum arabic and gum karoya.

12. The method of claim 11 wherein the hydrocolloid is selected from the group consisting of polyvinyl pyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose.

13. The method of claim 11 wherein the hydrocolloid comprises polyvinyl pyrrolidone.

14. ~~Granulated microcrystalline cellulose made by the process of claim 1.~~

15. ~~Granulated microcrystalline cellulose made by the process of claim 7.~~

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16. Microcrystalline cellulose granules having an irregular shape, a loose bulk density of from about 0.2 g/cc to about 0.4 g/cc and a mean particle size of from about 200 microns to about 1500 microns.

17. Microcrystalline cellulose granules as claimed in claim 16 having a loose bulk density of from about 0.25 g/cc to about 0.35 g/cc.

18. Microcrystalline cellulose granules as claimed in claim 16 having a mean particle size of from about 250 microns to about 1000 microns.

19. Microcrystalline cellulose granules as claimed in claim 16 having a mean particle size of from about 400 microns to about 900 microns.

20. Microcrystalline cellulose granules as claimed in claim 16 further comprising from about 1% to about 30% by weight, of a hydrocolloid, based on the weight of the microcrystalline cellulose granules.

21. Microcrystalline cellulose granules as claimed in claim 20 wherein the hydrocolloid comprises one or more hydrocolloids selected from the group consisting of: methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, hydroxypropyl methylcellulose, gelatin, water soluble cellulose acetate, polyvinyl pyrrolidone, starches, alginates, alginic acid, locust bean seed extract, guar seed extract, carrageenan, gum tragacanth, gum arabic and gum karoya.

22. Microcrystalline cellulose granules as claimed in claim 21 wherein the hydrocolloid is selected from the group consisting of polyvinyl pyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose.

23. Microcrystalline cellulose granules as claimed in claim 21 wherein the hydrocolloid comprises polyvinyl pyrrolidone.

24. A tablet which comprises from about 5% to about 80% by weight of granulated microcrystalline cellulose as claimed in claim 16; from about 5% to about

80% by weight of one or more of controlled release particles and barrier coated materials which contain an active ingredient; and from 0% to about 20% by weight of other excipients, based on the total weight of the tablet.

25. A tablet which comprises from about 5% to about 80% by weight of
5 granulated microcrystalline cellulose as claimed in claim 20; from about 5% to about 80% by weight of one or more of controlled release particles and barrier coated materials which contain an active ingredient; and 0% to about 20% by weight of other excipients, based on the total weight of the tablet.

26. A tablet which comprises from about 5% to about 80% by weight of
10 granulated microcrystalline cellulose as claimed in claim 23; from about 5% to about 80% by weight of one or more of controlled release particles and barrier coated materials which contain an active ingredient; and 0% to about 20% by weight of other excipients, based on the total weight of the tablet.